

Remarks

This Amendment is responsive to the Office Action mailed June 4, 2004, in connection with the above-identified patent application. In that Action, the drawings were objected to because, according to the Examiner, they did not include several reference sign(s) mentioned in the description. The same objections were applied to the specification by the Examiner.

Claims 1-11 and 24-28 are pending in this application. Among them, claims 1, 2, 6-11, 24, 25, 27, and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,972,143 to Stevens. Claims 3 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens. Claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,147,315 to Weber. Lastly, claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of Weber and further in view of U.S. Patent No. 5,843,051 to Adams, et al.

THE NON-ART MATTERS

As noted above, the drawings were objected to because, according to the Examiner, they do not include several reference sign(s) mentioned in the description. The drawings were objected to as failing to comply with 37 C.F.R. § 1.84(p)(5). The Examiner required a proposed drawing correction or corrected drawings because, according to him, they do not include reference sign(s) for: a first end, a second end; a first flexible outer coating; a second flexible outer coating; a first portion; a first transition area and a second portion. The Examiner further noticed that the same objections apply to the specification.

The Drawings are in Proper Form:

Applicant has tendered a proposed drawing correction to Figure 4b in an attached Request for Amendment to the Drawings. In that drawing correction, the first and second ends of the subject catheter are identified. The first and second flexible outer coatings have already been identified at reference numerals 58 and 62, respectively. The first portion of the catheter is identified in the drawing figures at reference numeral 74 and the second portion of the catheter is identified in the

drawing figures at reference numeral 72. Reference numeral 73 has been added to identify the first transition area between the first and second portions of the catheter.

It is respectfully submitted that no new matter has been added. Support is found in the specification as originally filed at least in the areas beginning on page 4 at line 19 and in the claims.

The Specification is in Proper Form:

Applicant has tendered an amendment to page 14 of the specification to place it in better conformance with the drawing figures as amended.

It is respectfully submitted that no new matter has been added. More particularly, support is found for the changes to the specification tendered above in the specification and claims as originally filed and, particularly, beginning at page 4, line 19 and in the claims.

For at least the above reasons, it is respectfully submitted that the specification is in proper form.

THE ART REJECTIONS

As noted above, claims 1, 2, 6-11, 24, 25, 27, and 28 were rejected as being anticipated by Stevens. Claims 3 and 26 were rejected as being unpatentable over Stevens. Claim 4 was rejected as being unpatentable over Stevens in view of Weber. Lastly, claim 5 was rejected as being unpatentable over Stevens in view of Adams, et al.

The Present Application:

For purposes of review, the subject application is directed to a reinforced catheter device including a coil reinforcement member carried on an inner tubular member, the coil reinforcement member being layered by first and second flexible outer coatings. The continuous coil reinforcement member is carried on the elongate flexible tubular member and extends from the proximal end of the catheter to the distal end of the catheter. First and second continuous flexible coatings cover the coil reinforcement member and the tubular member in an overlapping fashion substantially entirely between the proximal end of the catheter and the distal end of

the catheter. The outer coating is harder than the inner coating and is selectively removed over a length of the catheter to provide a thin flexible tip portion of the catheter. As described in the specification, the coil reinforcement member is disposed in the flexible tip portion as well as in the main body or proximal end of the catheter.

U.S. Patent No. 5,972,143 to Stevens:

U.S. Patent No. 5,972,143 to Stevens teaches a catheter including a coil reinforcement member covered in a practical sense by only a single flexible outer coating. In addition, the coil reinforcement member does not extend the entire end of the catheter but, however, is removed from a distal tip portion therein.

As described in the Stevens '143 patent, a braided overlay is adhered to an inner tubular member using a suitable bonding agent such as a UV curable epoxy coating. It is suggested at the top of column 7 of the '143 patent that a urethane or a nylon material can be used as a bonding agent.

After the reinforcement wire is braided onto the underlying tubular member, a thin secondary plastic coating is applied. It penetrates between the strands of wire braid and mechanically locks the stainless steel wires in place so that they do not unravel during a subsequent grinding operation intended to remove portions of the braided reinforcement wire along the length of the catheter. After the braid has been removed in selected areas (distal tip portion), the braided and non-braided continuous section of catheter stock is processed through a plastic extruder whereby a finish coat of an elastomer is applied to a uniform diameter.

Claims 1 and 3-11 are in Condition for Allowance:

Independent claim 1 recites a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the flexible tubular member, and first and second outer coatings covering the coil reinforcement member, the first coating being softer than the second coating. The elongate flexible tubular member defines a lumen of the catheter and has a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The continuous coil reinforcement member is carried on the elongate

flexible tubular member and extends from the proximal end of the catheter to the distal end of the catheter. The first outer coating covers the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating between a first transition area of the catheter and the proximal end of the catheter. The second portion of the first outer coating is uncovered by the second outer coating and defines a flexible distal tip of the catheter.

It is respectfully submitted that the prior art of record does not teach or suggest such a construction. More particularly, in the primary reference cited by the Examiner, namely the Stevens '143 patent, it is respectfully submitted that there is no teaching of first and second continuous flexible coatings covering a coil reinforcement member with the outer coating being harder than the inner coating. At best, in the Stevens '143 patent, the extruded thin coat is meant simply to adhere the braided steel reinforcement member onto the underlying tubular body. In addition to the above, nowhere in the Stevens '143 patent is there a teaching that the hardness of the bonding layer relative to the outer coating is of any significance. Still further, in the Stevens '143 patent, a portion of the stainless steel reinforcement member is ground away prior to the application of the single outer flexible coating. Thus, the reinforcement member in the prior art does not extend fully between the proximal end of the catheter and the distal end of the catheter.

The above limitations are clearly recited in independent claim 1 as amended above. For at least these reasons, it is respectfully submitted that independent claim 1 and claims 3-11 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 24-28 are in Condition for Allowance:

Independent claim 24 recites a reinforced catheter stock for manufacturing reinforced catheters. The catheter stock comprises a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock; a continuous coil

reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and, a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

Again, it is respectfully submitted that the art of record does not teach or suggest a catheter stock for making a reinforced catheter having a continuous coil reinforcement member extending from one end of the catheter to the opposite end and having first and second outer coatings of first and second materials, respectfully, covering the coil reinforcement member wherein the outer coating is harder than the inner coating and a portion of the outer coating being selectively removable from the inner coating to expose a soft distal tip portion of the catheter.

For at least the above reasons, it is respectfully submitted that independent claim 24 as amended above and claims 26-28 dependent therefrom are patentable distinct and unobvious over the art of record.

Conclusion

In view of the comments and arguments presented above, applicant respectfully submits that all pending claims are in condition for allowance.

Allowance of all pending claims and early notice to that effect is respectfully requested.

Respectfully submitted,

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07 SEP 04
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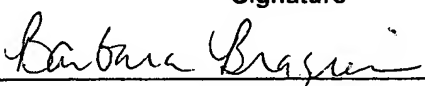
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Certificate of Mailing

Under 37 C.F.R. § 1.8, I certify that this **Amendment A** is being

- ☒ deposited with the United States Postal Service as First Class mail, addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.
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